REMARKS

This Amendment is responsive to the Office Action dated March 29, 2006. Applicants have amended claims 6, 27 and 52, and added new claims 63-65. Claims 1-65 are pending.

Allowable Subject Matter

The Office Action indicated that claims 9, 13, 14, 31, 36, 40, 55, 59 and 60 would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims. Applicant appreciates this indication of allowability for claims 9, 13, 14, 31, 36, 40, 55, 59 and 60.

However, for at least the reasons given below, Applicant respectfully suggests that independent claims 1, 17 and 47 are in condition for allowance. Therefore, at this time, Applicants do not amend dependent claims 9, 13, 14, 31, 36, 40, 55, 59 and 60 to place them into independent form.

Claim Rejection Under 35 U.S.C. § 103

The Office Action rejected claims 1-8, 10-12, 15-30, 32-35, 37-39, 41-54, 56-58, 61 and 62 under 35 U.S.C. § 103(a) as being unpatentable over Mann (US 6,052,624). Applicants respectfully traverse the rejection to the extent such rejection may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicants' claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Independent claims 1, 17 and 47

In support of the rejection, the Office Action asserted that that the mapping procedure outlined in the Mann reference is considered analogous to, and therefore obvious over, the calibration called for in Applicants' claims. Applicants respectfully disagree with this assertion.

Mann fails to teach or suggest calibrating a map that maps an output of a control device to values of at least one electrical stimulation parameter of a stimulation device, as required by Applicants' independent claims 1, 17 and 47. Mann merely describes a mapping procedure that includes defining a group of electrodes, which further defines a stimulation area, with an

electrode group location/size map generator circuit based on directional signals from the control device. More specifically, in Col. 9, ll. 41-51, Mann states that "control device 12 and selector button 42 provide signals to an electrode group location/size map generator circuit 50 that defines a group 45 of electrodes 24 within the array 23 of electrodes." Mann fails to describe, or even suggest, either **calibrating** or otherwise **adjusting** the electrode group location/size map.

In apparent recognition of the failure of Mann to suggest calibrating as required by the independent claims, the Office Action stated that one of ordinary skill in the art would understand that a certain amount of "personalization" of the device is necessary with the device described by Mann, since each patient is different and requires different stimulation patterns and parameters. This statement falls well short of the evidentiary standard for a prima facie case of obviousness, as established by clear Federal Circuit precedent.

It is well established that the Examiner bears the burden of establishing a prima facie case of obviousness.[1] In doing so, the Examiner must determine whether the prior art provides a "teaching or suggestion to one of ordinary skill in the art to make the changes that would produce" the claimed invention.[2] This finding must be based upon substantial evidence, and not subjective musings or conjecture by the Examiner.[3] A prima facie case of obviousness is established only when this burden is met.

In the present case, the Office Action cited no evidence suggesting that the Mann device requires "personalization," much less evidence suggesting modification of the Mann device to calibrate a map that maps an output of a control device to values of at least one electrical stimulation parameter of a stimulation device, as required by the independent claims. Such a suggestion is certainly not found within Mann, which is the only evidence cited in the Office Action.

In fact, the statement "a certain amount of personalization of the device is necessary...since each patient is different and requires different stimulation patterns and parameters," appears to be nothing more than a paraphrased version of teachings such as "[c]alibrating the map allows the control device to be mapped precisely to unique electrode

---

[1] *In re Oetiker*, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).
[2] *In re Chu*, 36 USPQ2d 1089, 1094 (Fed. Cir. 1995) (emphasis added).
[3] *Id.*

positions and orientations, and unique anatomies and physiologies presented by different patients."[4] Such teachings are found within Applicant's disclosure, rather than the prior art cited in the Office Action. It is impermissible to rely on teachings within Applicant's disclosure as a motivation to modify Mann.[5]

Moreover, even if a very general suggestion to "personalize" a device were present in the prior art, such a vague suggestion would have been completely inadequate to cause a person of ordinary skill in the art to make the specific modifications to Mann necessary to meet the requirements of Applicants' independent claims. A mere suggestion to "personalize" would not have suggested modifying the Mann device to calibrate a map that maps an output of a control device to values of at least one electrical stimulation parameter of a stimulation device, as required by the independent claims.

In a similar manner, Mann fails to teach or suggest the features of dependent claims 2-8, 10-12, 15, 16, 18-30, 32-35, 37-39, 41-46, 48-54, 56-58, 61 and 62. For example, claims 4, 25 and 50 recite that calibrating a map comprises receiving outputs from the control device that reflect manipulation of the directional controller to a plurality of predetermined locations, receiving information that reflects paresthesia experienced by the patient when the directional controller is located at each of the locations, and adapting a fixed map based on the outputs and the paresthesia information. Mann does not describe calibrating the electrode group location/size map based on information received from a user of the control device that reflects paresthesia experienced by a patient. In fact, Mann does not describe receiving *any* patient feedback information from the user of the control device for calibration of the map.

Instead, Mann only describes the user of the control device responding to patient feedback by manipulating the directional control device. For example, in Col. 5, ll. 43-46, Mann states that the patient immediately responds to maneuvers of the control device conducted by a user that causes the user to move toward or away from certain directions. In addition, in the Summary, the Mann reference describes receiving directional signals to select a group of electrodes and receiving pulse-defining parameters for the group of electrodes from a user of the control device.

---

[4] Application, paragraph [0013].
[5] *In re Oetiker*, 24 USPQ2d at 1445.

None of these teachings of Mann is remotely related to calibration of a map, as required by Applicants' claims. Accordingly, Mann clearly fails to teach or suggest adapting a fixed map based on the directional output of the control device and the received patient paresthesia information from the user of the control device, as required by claims 4, 25 and 50. "Personalizing" the stimulation control device described by the Mann reference would not result adapting a fixed map based on the directional output of the control device and the received patient paresthesia information from the user of the control device, as required by claims 4, 25 and 50.

In addition, claims 6, 27 and 52 recite that the paresthesia information comprises at least one of an amplitude level associated with a stimulation perception threshold, and an outline of a paresthesia region on a body diagram. As described above, Mann does not describe receiving patient paresthesia feedback information from the user of the control device for calibration of the electrode group location/size map.

As another example, claims 11, 33 and 57 recite that calibrating a map comprises receiving paresthesia and positional reference information during testing of a plurality of values of the electrical parameter by application of electrical stimulation to the patient via the stimulation device according to the plurality of values, and continually calibrating the map based on the paresthesia and positional reference information. Again, Mann fails to describe calibrating the electrode group location/size map based on information received from a user of the control device that reflects paresthesia experienced by a patient. Mann also fails to describe receiving any patient feedback information from the user of the control device for calibration of the map. Clearly, Mann does not teach or suggest continual calibration of the map during testing based on the directional output of the control device and the received patient paresthesia information from the user of the control device.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicants' claims 1-8, 10-12, 15-30, 32-35, 37-39, 41-54, 56-58, 61 and 62 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

New Claims

Applicants have added new claims numbered 63-65 to the application. No new matter is added by the new claims. Further, Mann fails to disclose or suggest the requirements of the new claims. For example, for at least the reasons discussed above with reference to claims 4, 25 and 50, Mann fails to disclose or suggest calibrating a map that maps output of a control device to values of at least one electrical stimulation parameter of a stimulation device based on information received from a user of the control device that reflects paresthesia experienced by a patient, as required by each of new claims 63-65.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: 6/29/06

By: _____

SHUMAKER & SIEFFERT, P.A.
8425 Seasons Parkway, Suite 105
St. Paul, Minnesota 55125
Telephone: 651.735.1100
Facsimile: 651.735.1102

Name: Jason D. Kelly
Reg. No.: 54,213